

assimilable nitrogen and assimilable carbon and a source of assimilable phosphorus,

- C1
- (b) during a growth phase of the fermentation up to a fermentation time adding a further source of assimilable phosphorus to maintain the concentration of assimilable phosphorus between 0.0015% and 0.15% w/v, and optionally adding further sources of assimilable carbon and assimilable nitrogen during the fermentation, and
  - (c) subsequently isolating the clavulanic acid or a salt thereof from the fermentation broth.

93. The process of claim 74 where ammonium hydroxide or sodium hydroxide is added to the fermentation broth to control the pH of the broth during the fermentation.

94. The process of claim 74 where the process is a continuous fermentation with intermittent or continuous addition of a source of assimilable phosphorus.

---

#### REMARKS

Entry of this amendment is respectfully requested. No new matter is added by this amendment because added claim 56-94 are fully supported by the application as filed. In particular, claims 56-73 are essentially the claims of the application as filed (i.e. before the preliminary amendment) with multiple dependencies removed and minor editorial changes.

Claims 36-94 are in this application. Claims 36-55 were rejected under 35 USC 135(b). This rejection is respectfully traversed as applied to claims 36-94.

Claims 36-55 were rejected under 35 USC 135(b) as not being made prior to one year from the date on which US Patent No. 6,100,052 was granted, with the Examiner stating that:

"Specifically, claims 36-55 recite subject matter clearly overlapping and/or encompassing and/or suggested by the subject matter recited in the patented claims. Note specifically that both sets of claims recite the two-stage maintenance of phosphorus concentration, and that applicant's claims clearly recite ranges which are encompassed by the patented claims. Thus claims 36-55 are clearly directed to "substantially the same subject matter" as stated in 35 USC 135(b). Moreover, the first appearance of these claims was on September 28, 2001, more than one year after the August 8, 2000, issue date of the '052 patent. Thus, rejection under 35 USC 135(b) is clearly required."

Applicants respectfully disagree.

While 35 USC 135(b)(1) does provide that "A claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent may not be made in any application unless such a claim is made prior to one year from the date on which the patent was granted", this statute does not bar claims 36-94.

With respect to claims 56-73, these claims, remade in the application by this amendment, were present in substantially the same form in the application as filed, and thus were made in this application well before the issue date of the '052 patent, and indeed before the US filing date (35 USC 102(e) date) of the application that became the '052 patent, because the claims were presented in the PCT application as filed on April 11, 1997.

With respect to claims 36-55 and 74-94, these claims find substantial basis in the claims of the application as filed (Claims 1-18), and are therefore supported by these claims in a manner that prohibits the application of 35 USC 135(b)(1). For example, claim 36, which requires an initial phosphorus concentration of less than 0.15% and addition of phosphorus during the fermentation to maintain the phosphorus concentration between 0.0015% and 0.15%, is substantially claim 5 of the application as filed (albeit without claim 5's limitation that the concentration is maintained up to a fermentation time of 40 hours), with the language on "addition of ... phosphorus to maintain" the concentration being inherent in claim 5's

limitation on the phosphorus concentration. Other claims are similarly supported. Thus, each of the claims finds support in the claims of the application as filed and is therefore not made more than one year after the issue date of the '052 patent.

It should be noted that 35 USC 135(b)(1) cannot be a bar to the presentation of any claim "for the same or substantially the same subject matter as, a claim of an issued patent" *in the abstract* - it must be read only as barring the presentation of claims that are completely new to the application; for otherwise, for example, the presentation of a claim within the one-year period permitted by 35 USC 135(b)(1) followed by its replacement with a new claim instead of the amendment of that claim would result in a bar to the presentation of the new claim, a totally illogical result.

Second, while applicants concede that certain of the claims, such as claim 36, are indeed broader than the claims of the '052 patent, other claims, such as claim 37, are not. Claim 37 requires that the concentration of assimilable phosphorus be allowed to decrease after cessation of the growth phase of the fermentation, a feature neither disclosed nor suggested by the claims of the '052 patent. Similarly, the fermentation time of 40 hours in claim 38 is neither disclosed nor suggested by the claims of the '052 patent. Claims 39 and 40 also contain the 40 hour limitation. Claims 41 and 41 require the concentration at the starting stage to be about 0.008%, again neither disclosed nor suggested by the claims of the '052 patent. Claims 43 and 44 contain limitations as to the nitrogen source, again neither disclosed nor suggested by the claims of the '052 patent. Claim 50 requires a limitation on the carbon concentration, again neither disclosed nor suggested by the claims of the '052 patent. Claims 51 and 52 require limitations on the nitrogen source and concentration, again neither disclosed nor suggested by the claims of the '052 patent. Claims 53 and 54 require limitations on the size of the fermentation batch (the fermentation volume), again neither disclosed nor suggested by the claims of the '052 patent. Similar limitations are seen in the sets of claims constituted by claims 56-73 and 74-94.

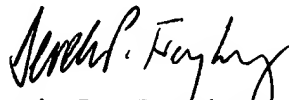
It is recognized that 35 USC 135(b)(1) does not act as a bar to the presentation of claims to subject matter that is

patentably distinct from the claims of a patent issuing more than one year before, as seen in *In re Sasse*, 207 USPQ 107 (CCPA, 1980), where the then 35 USC 135(b) was held not to bar claims to a species within a genus claimed in a patent issuing more than one year before the presentation of the species claims. The Examiner's conclusory statements that the claims are "clearly overlapping and/or encompassing and/or suggested by the subject matter recited in the patented claims" does not constitute a proper statement of a rejection of claims under 35 USC 135(b)(1) any more than such a statement would be proper in a rejection under 35 USC 103(a): to the extent any claim is different from the claims of the '052 patent, it is incumbent on the Examiner to demonstrate why each is for "for the same or substantially the same subject matter as, a claim of an issued patent" for a rejection under 35 USC 135(b)(1) to be proper, and this he has not done.

#### Conclusion

For the reasons given above, Applicants respectfully submit that Claims 36-55 (and added claims 56-94) are not subject to rejection under 35 USC 135(b)(1). Withdrawal of the rejection, and allowance of the claims, are respectfully requested.

Respectfully submitted,



Derek P. Freyberg  
Attorney for Applicants  
Reg. No. 29,250

Customer No. 25213  
Heller Ehrman White & McAuliffe LLP  
275 Middlefield Road  
Menlo Park CA 94025-3506  
(650) 324-7014  
October 30, 2002